REMARKS

Applicant respectfully requests reconsideration of the present application in view of the reasons that follow. Claims 20-22 and 25-45 are now pending in this application, and are submitted for reconsideration.

Rejection of claims 20-22, 25, 30, and 40

Claims 20-22, 25, 30, and 40 are rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over U.S. Patent 3,586,649 ("Cobbledick") and U.S. Patent 3,258,511 ("McGregor"). For at least the following reasons, this rejection is traversed.

Claim 20 recites, among other things, an upholstery part comprising: a foam body; and a protective layer arranged at least at a partial region of a foam body surface. The protective layer contains polyvinyl acetate that can be applied in liquid form and cured.

Cobbledick and McGregor do not teach or suggest the combination of features of claim 20. For instance, neither Cobbledick nor McGregor teaches or suggests a protective layer containing polyvinyl acetate that can be applied in liquid form and cured. The PTO acknowledges that Cobbledick does not disclose polyvinyl acetate by stating that: "Cobbledick is silent that the vinyl plastic is polyvinyl acetate." (Page 3 of the Office Action.) McGregor does not cure the deficiency of Cobbledick because McGregor does not teach or suggest the use of polyvinyl acetate either. The PTO asserts that:

McGregnor's [sic] invention relates to polyurethane foam for upholstering furniture [col. 1, ll. 16-18]. An impervious film is provided over the porous surface of the foam [col. 1, ll. 69-72]. Useful films include homopolymer of vinyl acetate [col. 2, ll. 58-63]. It would have been obvious to one of ordinary skill in the art to use polyvinyl acetate as the vinyl plastic in Cobbledick's foam for upholstering because the selection of a known material based on its suitability for its intended use supported a *prima facie* obviousness determination. See MPEP § 2144.07. (Page 2 of the Office Action.)

However, it is respectfully submitted that McGregor does not teach or suggest the use of polyvinyl acetate in any passages cited by the PTO or anywhere else in Cobbledick or McGregor. For example, the PTO cites column 2, lines 58-63 of McGregor for supporting the assertion that McGregor discloses "[u]seful films include homopolymer of vinyl acetate." This passage is provided below:

The thermoplastic sheets employed also may be fabricated from blends of two or more polymeric materials, e.g., blends of polyvinyl chloride and butadiene-acrylonitrile interpolymers, blends of polystyrene with rubbery diene polymers such as natural rubber, butadiene-styrene interpolymers and butadiene-acrylonitrile interpolymers, etc. or high impact polystyrene prepared by polymerizing monomeric styrene in the presence of rubbery diene polymers. In all cases, the film must be impervious and substantially insoluble in the foamable resin composition used to form the cushion or cushioned article.

Nowhere in this passage is polyvinyl acetate or a "homopolymer of vinyl acetate" mentioned. Vinyl acetate is mentioned in the below passage from column 2, lines 34-54 of McGregor:

Any suitable film can be used as the impervious layer 35 such as, for example, non-porous polyurethane or those prepared from cellulose ethers and esters, e.g., methyl cellulose, ethyl cellulose, cellulose nitrate, cellulose acetate, cellulose butyrate, cellulose acetatebutyrate; homopolymers and interpolymers derived from monomers con-40 taining the vinylidene CH₂=C< group such as vinyl halides, e.g., vinyl chloride, vinyl bromide; vinylidene chloride; olefins, e.g., ethylene, isobutylene; vinyl esters of carboxylic acids, e.g., vinyl acetate, vinyl propionate, vinyl benzoate; vinyl esters, e.g., vinyl methyl ether, vinyl isobutyl ether; unsaturated carboxylic acids and derivatives thereof, e.g., acrylic acid, acryl c acid esters, acrylamide, acrylonitrile, methacrylic acid and its corresponding derivatives; vinyl aromatic compounds, e.g., styrene, vinyl tolurene, alpha-methylstyrene, o-chlorostyrene, 2,5dichlorostyrene, 2,4-dimethylstyrene; and interpolymers of such vinylidene monomers with alpha, beta-unsaturated polycarboxylic acids and derivatives thereof, e.g., maleic anhydride, diethyl maleate, dibutyl fumarate, and diallyl maleate.

In the above passage, two considerations are noted. First, the laundry list of possible materials uses semi-colons to separate different material groups. Second, the material group of "vinyl esters" is separated from the material group of "homopolymers and interpolymers derived from monomers containing the vinylidene CH₂=C<group, such as vinyl halides" by the material groups of "vinylidene chloride" and "olefins" and corresponding semicolons separating the listing of these material groups. Thus, McGregor does not explicitly disclose "homopolymers of vinyl acetate" but only refers to "vinyl esters of carboxylic acid," such as vinyl acetate.

At best, McGregor discloses that "vinyl esters of carboxylic acids, e.g., vinyl acetate" can be used as the impervious film. (See the underlined portion in the above passage.) Vinyl acetate is a monomer while polyvinyl acetate is produced by the polymerization of the vinyl

acetate monomer. (See the definition of polyvinyl acetate from the website of a plastic industry trade association (SPI) in Appendix A.) Polyvinyl acetate is prepared by treating the monomer vinyl acetate with peroxide catalysts.

The issue becomes does the disclosed vinyl acetate in McGregor refer to the monomer vinyl acetate or polyvinyl acetate? One of ordinary skill in the art would believe that monomer vinyl acetate was being referenced in McGregor, and not polyvinyl acetate. First, McGregor did not use the "homopolymer or interpolymer" language in conjunction with the vinyl acetate language, as was done in other passages, thus its omission must have been intended. Second, McGregor did not use "poly" in conjunction with the vinyl acetate language, as was one with other compounds.² Third, Appendix B from the Vinyl Acetate Counsil discloses vinyl acetate (VA) vinyl ester copolymer and polyvinyl acetate as different materials when discussing the end uses of various VA monomer-based polymers, i.e., polyvinyl acetate and VA vinyl ester copolymer are listed separately. Also, polyvinyl acetate has different applications including printing ink, lacquer, adhesive, plastic, paper finishing, and textile finishing from that of VA vinyl ester copolymer, which is used in cosmetics. (See Appendix B.) Thus, one of ordinary skill in the art would recognize that polyvinyl acetate and VA vinyl ester copolymer exist as two different materials.³ Finally, one of ordinary skill in the art would interpret McGregor to mean what it says. If McGregor discloses vinyl acetate, and such a material exists, one or ordinary skill in the art would not interpret such a disclosure to mean polyvinyl acetate. Given the above, because McGregor merely discloses the use of vinyl acetate, one of ordinary skill in the art would not interpret McGregor to teach the use of polyvinyl acetate as a protective layer arranged on a foam body.

¹ For example, McGregor refers to the "interpolymers of such vinylidene monomers with alpha, beta-unsaturated polycarboxylic acids and derivatives thereof, e.g., maleic anhydride, diethyl maleate, dibutyl fumarae, and diallyl maleate" in the same laundry list of vinyl acetate. (Column 2, lines 50-54 of McGregor.)

² For example, McGregor refers to polyvinyl chloride, not simply vinyl chloride. Column 2, lines 55-57 of McGregor.) Polyvinyl chloride is made by polymerization of the monomer vinyl chloride while polyvinyl acetate is made by polymerization of vinyl acetate.

³ Appendix C is a chronic toxicity summary report for vinyl acetate from the website http://www.oehha.org/air/chronic_rels/pdf/vinylace.pdf that discloses vinyl acetate monomer is used in the manufacture of polyvinyl and vinyl acetate copolymer. This disclosure also shows that polyvinyl acetate and vinyl acetate copolymer are different materials.

Because Cobbledick and McGregor does not teach or suggest a protective layer containing polyvinyl acetate that can be applied in liquid form and cured, claim 20 is allowable.

Furthermore, the rejection based on Cobbledick and McGregor is improper because Cobbledick teaches away from the combination. Cobbledick discloses a non-rigid polyurethane foam structure having an integral skin to which surface coatings may be applied. (Column 1, lines 13-21 of Cobbledick.) The purpose of the invention of Cobbledick is to create an integral skin for the foam structure "without the need to apply skin-forming composition to the shaping mold before the casting of the foam-forming composition." (Column 2, lines 43-46 of Cobbledick.) Further, the method of Cobbledick relates to removing the need to apply a protective layer in liquid form by including a combination of an aryl diamine and a polyhydroxy containing graft polymer of an unsaturated monomer on a polyol backbone polymer. (Column 3, lines 64-69 of Cobbledick.) In other words, the process of Cobbledick is removing the need to apply a protective layer in liquid form to a region of a foam body surface. The passage of column 2, lines 2-15 of Cobbledick (which the PTO cites for supporting the teaching of spraying a film on a foam body) discloses a method from which Cobbledick is teaching away. MPEP 2145 provides that "[i]t is improper to combine references where the references teach away from their combination. In re Grasselli, 713 F.2d 731, 743, 218 USPQ 769, 779 (Fed. Cir. 1983)." Thus, one of ordinary skill in the art would not combine the teachings of Cobbledick and McGregor because Cobbledick teaches away from such a combination. Thus, claim 20 is allowable over Cobbledick and McGregor.

Claims 21-22, 25, and 30 depend from and contain all the features of claim 20, and are allowable for the same reasons as claim 20, without regard to the further patentable features contained therein.

Claim 40 recites, among other things, an upholstery part comprising: a foam body moldable in a mold; and a protective coating at least partially covering a surface of the foam body. The protective coating is applied in liquid form to at least one of the mold and the foam body surface and cured thereafter. The protective coating comprises polyvinyl acetate.

Cobbledick and McGregor do not teach or suggest the combination of features of claim 40. For instance, and as previously mentioned, neither Cobbledick nor McGregor

teaches or suggests a protective layer comprising polyvinyl acetate that can be applied in liquid form and cured. Also, the rejection based on Cobbledick and McGregor is improper because Cobbledick teaches away from the combination. Thus, claim 40 is allowable over Cobbledick and McGregor.

For at least these reasons, favorable reconsideration of the rejection is respectfully requested.

Conclusion

Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing or a credit card payment form being unsigned, providing incorrect information resulting in a rejected credit card transaction, or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

FOLEY & LARDNER LLP

Customer Number: 22428 Telephone:

Facsimile:

(202) 672-5349

(202) 672-5399

Matthew J. Kremer

Attorney for Applicant

Registration No. 58,671

APPENDIX A:

WEB PAGE FROM THE WEBSITE OF SPI, A PLASTICS INDUSTRY TRADE ASSOCIATION

Definition of Resins - Polyvinyl Acetate (PVAx) & Other Vinyls



Home > About Plastics > Glossary

Definitions of Resins - Polyvinyl Acetate (PVAc) & Other Vinyls

Polyvinyl acetate is a thermoplastic resin produced by the polymerization of vinyl acetate monomer [CH₃COOCHCH₂] in water producing an emulsion with a solids content of 50-55%. Most polyvinyl acetate emulsions contain co-monomers such as n-butyl acrylate, 2-ethyl hexyl acrylate, ethylene, dibutyl maleate and dibutyl fumarate. Polymerization of vinyl acetate with ethylene also can be used to produce solid vinyl acetate/ethylene copolymers with more than 50% vinyl acetate content. Polyvinyl alcohol (PVOH) is produced by methanolysis or hydrolysis of polyvinyl acetates. The reaction can be controlled to produce any degree of replacement of acetate groups. Co-polymers of replaced acetate groupings and other monomers such as ethylene and acrylate esters are commercially important. Polyvinyl butyral (PVB) is made by reacting PVOH with butyraldehyde [CH₃(CH₂)₂CHO]. Polyvinyl formal is made by condensing formaldehyde [HCHO] in presence of PVOH or by the simultaneous hydrolysis and acetylization of PVAc. Polyvinylidene chloride is made by the polymerization of 1,1-dichloroethylene [CH₂CCL₂]. Typical applications for the above resins are adhesives, paints, coatings and finishes, and packaging.

Home | Contact Us 1667 K St., NW, Suite 1000 - Washington, DC 20006 phone 202.974.5200 fax 202.296.7005

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APPENDIX B

WEB PAGE FROM THE WEBSITE OF THE VINYL ACETATE COUNSIL

What is Vinyl Acetate

http://www.vinylacetate.org/what.shtml

What is Vinyl Acetate?

Vinyl acetate is a versatile and economically important chemical with a wide variety of industrial and commercial applications.

Synonyms:

Vinyl Ester Acetic Acid

Ethenyl Ester

Vinyl Acetate Monomer

VAM

Ethenyl Acetate 1-Acetoxyethylene

CAS Name

Ethenyl Ester

CAS Registry Number

108-05-4

Chemical Formula

CH₃COOCH=CH₂

Chemical Structure

Uses

Vinyl acetate monomer is a chemical building block used to manufacture a wide variety of polymers including: polyvinyl acetate; polyvinyl alcohol; polyvinyl acetals; ethylene vinyl acetate copolymers, ethylene vinyl alcohol and several others shown in the table below. VAM-based polymers are commonly used in the production of:

- plastics
- films
- lacquers
- laminating adhesives
- elastomers
- inks
- · water-based emulsion paints
- adhesives
- finishing and impregnation materials
- paper coatings
- floor tiling
- safety glass
- building construction
- acrylic fibers
- glue
- cosmetics and personal care products
- textile finishing and non-wovens

The table shows several of the end uses for various VAM-based polymers. This information is based on the May 2008 draft EU human health risk assessment for VAM, Canada's May 2008 draft Screening Assessment for VAM, and the US Department of Human Health's Household Products Database.

					Building material	Printing ink	Paint / Coatings	Film	Lacquer	Adhesive	Cosmetics	Plastic	Paper finishing	Textile finishing	Non woven	Pesticides
. VAM	+	VAM	→	polyvinyl acetate	x	x	x		x	x		x	x	X		
VAM	+	acrylate	→	vinyl acrylic co-polymer	X		x						x	X	x	×
VAM	+	ethylene	→	EVA				х		x		x				
VAM	+	ethylene	→	VAE	x		x			×		x	x	×	x	_
VAM	+	vinyl chloride	→	VC copolymer		x			х	x		х	х		х	
VAM	+	carbonic acid	→	VA carbonic acid copolymer							x					
VAM	+	vinyl ester	→	VA vinyl ester copolymer	×		x				x					
VAM	+	vinyl alcohol	→	VA vinyt alcohol copolymer						x						x
VAM	+	crotonic acid	→	VA crontonic acid copolymer							x					
VAM	+	crotonic acid + vinyl neo-		VA crotonic acid neodecanoate copolymer							x					
			decanoate		7	VA crotonic acid vinyl neodecanoate (tetra)polymer							x			
VAM	+	polyvinyl- pyrrolidone	→	VA polyvinyl pyrrolidone copolymer				_								x
VAM	+	dioctyl maleate	→	VA, dioctyl maleate copolymer	x					x						
VAM	+	vinyl chloride + maleic anhydride	→	VA, vinyl chloride, maleic anhydride polymer	x											

Additional Information

General Properties of Vinyl Acetate, including physico-chemical data

Health and Environmental Effects

APPENDIX C

CHRONIC TOXICITY SUMMARY: VINYL ACETATE

http://www.oehha.org/air/chronic_rels/pdf/vinylace.pdf

CHRONIC TOXICITY SUMMARY

VINYL ACETATE

(1-acetoxyethylene; acetic acid, vinyl ester; acetic acid, ethenyl ester; VAC; vinyl A monomer: ethenyl ethanoate)

CAS Registry Number: 108-05-4

I. **Chronic Toxicity Summary**

Inhalation reference exposure level 200 µg/m³ (50 ppb)

Critical effect(s)

Nasal epithelial lesions in rats and mice

Hazard index target(s)

Respiratory system

II. Physical and Chemical Properties (HSDB, 1994)

Description

Colorless liquid

Molecular formula

 $C_4H_6O_2$ 86.09 g/mol

Molecular weight Density

0.932 g/cm³ @ 20°C

Boiling point

72.7° C

Melting point Vapor pressure -93.2°C 115 torr @ 25°C

Solubility

Slightly soluble in water, soluble in ethane, acetone, chloroform; >10% soluble in ethanol and benzene

Conversion factor

1 ppm = $3.52 \text{ mg/m}^3 @ 25^{\circ}\text{C}$

III. **Major Uses and Sources**

The major use of vinyl acetate monomer is in the manufacture of polyvinyl and vinyl acetate copolymers, which are used in water-based paints, adhesives, paper coatings, and applications not requiring service at extreme temperatures (HSDB, 1994). It is also used in safety glass interlayers and in hair sprays (HSDB, 1994). In the atmosphere vinyl acetate breakdown can result in formation of acetaldehyde. The annual statewide industrial emissions from facilities reporting under the Air Toxics Hot Spots Act in California based on the most recent inventory were estimated to be 3855 pounds of vinyl acetate (CARB, 2000).

IV. **Effects of Human Exposures**

Deese and Joyner (1969) conducted an occupational study of 21 chemical workers with a mean length of employment of 15.2 years and exposed to a time-weighted average of 8.6 ppm (30.3 mg/m³) VA. No adverse effects were noted following chest x-ray, electrocardiogram, blood chemistry, and urinalysis. The control group (sample size unspecified) consisted of workers in

> A - 109 Vinyl acetate

units not exposed to VA. Deese and Joyner (1969) also showed intolerable eye irritation in 3 out of 3 subjects exposed for an unspecified extended period of time to 21.6 ppm (76 mg/m³) VA. Upper respiratory irritation was also experienced by a majority of 5 subjects. Odor was detected at 0.4 ppm (1.4 mg/m³) in 3 out of 3 subjects.

V. Effects of Animal Exposures

A 104-week inhalation study in rats and mice (90/sex/group) was conducted using concentrations of 0, 50, 200, or 600 ppm (0, 176, 704, or 2113 mg/m³) vinyl acetate (VA) (Owen, 1988). The study was later published by Bogdanffy *et al.* (1994). Exposures were for 6 hours/day, 5 days/week. Histology was performed on all major organs. There was no mortality resulting from these exposures. A close examination of the effects of VA on the lung and nasal passages showed significant lesions in the nasal cavity, bronchi, and lungs of rats exposed to 600 ppm VA. Lesions included olfactory epithelial metaplasia/atrophy (see table below) and nest-like epithelial folds in the nasal cavity, exfoliation of bronchial epithelium, fibrous intraluminal projections in the bronchi, and pigmented histiocyte accumulation in the lungs. Body weight gain of rats was significantly decreased in the 600 ppm VA group. Rats treated with 200 ppm VA showed some evidence of epithelial atrophy and metaplasia in the nasal cavity. No effects were observed in the rats exposed to 50 ppm VA.

Number of male rats with olfactory epithelial atrophy (Bogdanffy et al. 1994)

VA (ppm)	N in group	Very slight	Slight	Moderate	Severe
0	58	0	0	0	0
50	59	1	2	0	0
200	60	4	47***	2	0
600	60	0	7*	33***	10***

^{*} p<0.05; ***p<0.001 by Fisher's pair-wise test compared to control group

Mice also exhibited significant histological lesions in the respiratory tract following exposure to 200 ppm VA or greater. The lesions included atrophy of the olfactory epithelium and submucosal gland. At 600 ppm, hyperplasia of the trachea was observed, in addition to exfoliation/flattening of the bronchial epithelium and decreased body weight gain. Relative brain and kidney weights were increased in the 600 ppm group at the end of the study, and absolute liver, heart and kidney weights were also significantly elevated. No adverse effects were observed in the 50 ppm group.

A 13-week study on the effects of VA in mice was conducted by Owen (1980a). Mice (10/sex/concentration) were exposed to 0, 50, 200, or 1000 ppm (0, 176, 704, or 3520 mg/m³) VA for 6 hours/day, 5 days/week for 13 weeks. A concentration-dependent increase in the incidence of diffuse rhinitis, beginning at the 200 ppm concentration, was detected using histopathological examination. Focal pneumonitis was observed in the 1000 ppm treatment group. No adverse effects were seen in the 50 ppm treatment group. An identical study in rats was also conducted by Owen (1980b). In this study, body weight gain was significantly reduced in male and female rats exposed to 1000 ppm VA. An increase in the incidence of mild histiocytic alveolitis was observed in the 1000 ppm group.

Irvine (1980) conducted a study on the developmental toxicity of VA in rats. Groups of 24 pregnant female rats were exposed to 0, 52, 198, or 1004 ppm (0, 182, 696, or 3533 mg/m³) VA for 6 hours/day on days 6-15 of gestation. Significant maternal toxicity, as measured by reduced weight gain from day 10 through day 15, was observed in animals exposed to 1004 ppm. Fetotoxicity, as measured by reduced crown-rump length, reduced body weight, and increased incidence of ossification defects in the sternebrae and occipital regions, was observed in the 1004 ppm group. No maternal or fetal effects were seen at the lower two VA treatments.

In another developmental toxicity study, groups of 23-24 Crl:CD(SD)BR rats were given 0, 200, 1000, or 5000 ppm VA in drinking water or exposed 6 hr/day to 0, 50, 200, or 1000 ppm VA on gestation days 6-15 of gestation. The authors (Hurtt et al., 1995) estimated that the doses by both routes were approximately 0, 25, 100, or 500 mg/kg/day. VA in the drinking water produced no evidence of maternal or developmental toxicity at any dose. In the inhalation study, maternal toxicity was indicated by a reduction in weight gain of dams exposed to 1000 ppm. Fetal toxicity was evident by a significant decrease in mean fetal weight and mean crown-rump length in fetuses from the 1000-ppm group and by a significant increase in the incidence of minor skeletal alterations (especially delayed ossification) in fetuses from dams exposed to 1000 ppm VA. These results indicated to the authors that VA is not uniquely toxic to the conceptus. The NOAEL was greater than 5000 ppm via the drinking water and 200 ppm by the inhalation route.

VI. Derivation of Chronic Reference Exposure Level

Study	Bogdanffy et al., 1994
Study population	Male and female Sprague-Dawley rats and CD-1 mice (90/sex/group)
Exposure method	Discontinuous inhalation exposures (0, 50, 200, or 600 ppm) over 104 weeks
Critical effects	Histological lesions of the nasal epithelium
LOAEL	200 ppm
NOAEL	50 ppm
Exposure continuity	6 hours/day, 5 days/week
Exposure duration	104 weeks
Average experimental exposure	8.9 ppm for NOAEL group (50 x 6/24 x 5/7)
Human Equivalent Concentration (HEC)	1.4 ppm for NOAEL group (RGDR = 0.15 based on a gas with respiratory effects in both rats and mice)
LOAEL uncertainty factor	1
Subchronic uncertainty factor	1.
Interspecies uncertainty factor	3
Intraspecies uncertainty factor	10
Cumulative uncertainty factor	30
Inhalation reference exposure level	$0.05 \text{ ppm } (50 \text{ ppb}, 0.2 \text{ mg/m}^3, 200 \mu\text{g/m}^3)$

The chronic REL is the U.S. EPA RfC (U.S. EPA, 1995) for vinyl acetate. Acetaldehyde, a hydrolysis product of vinyl acetate, was present in the Owen (1988) study at a concentration of 49 ppm (89 mg/m³). The duration-adjusted concentration for acetaldehyde was 16 mg/m³, whereas the NOAEL for histological lesions in rats by Appleman *et al.* (1982) was 48.75 mg/m³ acetaldehyde. Therefore, the concentration of acetaldehyde was not considered to account for significant irritation in the Owen (1988) study. OEHHA accepted the U.S. EPA analysis.

For comparison, Irvine (1980) obtained a NOAEL of 198 ppm for fetotoxicity in rats exposed 6 hours/day on days 6-15 of gestation. This is equivalent to 50 ppm continuous exposure during development. Multiplying by an RGDR of 1 and dividing by a total UF of 30 (3 for interspecies and 10 for intraspecies) results in a REL estimate based on fetotoxicity of 1.7 ppm. The results of Hurtt et al. (1995) also yield an estimate of 1.7 ppm.

VII. Data Strengths and Limitations for Development of the REL

The strengths of the inhalation REL for vinyl acetate include the availability of controlled exposure lifetime inhalation studies in multiple species at multiple exposure concentrations and with adequate histopathological analysis, and the observation of a NOAEL. The major area of uncertainty is the lack of adequate human exposure data.

VIII. Potential for Differential Impacts on Children's Health

Since the chronic REL (0.05 ppm) is lower than the comparison estimate based on developmental effects (1.7 ppm), the REL is likely to be protective of children. However, there is no direct evidence in the literature to quantify a differential effect of vinyl acetate in infants and children relative to adults.

IX. References

Appleman LM, Woutersen RA, and Feron VJ. 1982. Inhalation toxicity of acetaldehyde in rats. I. Acute and subacute studies. Toxicology 23:293-307.

Beems RB. 1988. Report No. V 88.133: Histopathology of the respiratory tract of mice used in a 104-week inhalation study with vinyl acetate. (TNO-CIVO Institutes, April 1988).

Bogdanffy MS, Dreef-van Der Meulen HC, Beems RB, Feron VJ, Cascier TC, Tyler TR, Vinegar MB, and Rickard RW. 1994. Chronic toxicity and oncogenicity inhalation study with vinyl acetate in the rat and mouse. Fundam. Appl. Toxicol. 23:215-229.

CARB. 2000. California Air Resources Board. California Emissions Inventory Development and Reporting System (CEIDARS). Data from Data Base Year 1998. February 12, 2000.

A - 112 Vinyl acetate Deese DE, and Joyner RE. 1969. Vinyl acetate: A study of chronic human exposure. Am. Ind. Hyg. Assoc. J. 30:449-457.

Dreef-van der Meulen HC. 1988. Report No. V 88.033/270836: Histopathology of the respiratory tract of rats used in a 104 week inhalation study with vinyl acetate: Revised version. (TNO-CIVO Institutes, October 1988).

HSDB. 1994. Hazardous Substances Data Bank. National Library of Medicine, Bethesda, MD (TOMES® CD-ROM version). Denver, CO: Micromedex, Inc. (Edition expires 11/31/94).

Irvine LFH. 1980. Vinyl acetate oral and inhalation teratology studies in the rat. Report prepared by Hazelton Laboratories Europe Ltd., Harrogate, England for the Society of the Plastics Industry, Inc., New York. Report No. 2195-51/6&7.

Owen PE. 1980a. Vinyl acetate: 3 month inhalation toxicity study in the mouse. Report prepared by Hazelton Laboratories Europe Ltd., Harrogate, England for the Society of the Plastics Industry, Inc., New York. Report No. 2303-51/5.

Owen PE. 1980b. Vinyl acetate: 3 month inhalation toxicity study in the rat. Report prepared by Hazelton Laboratories Europe Ltd., Harrogate, England for the Society of the Plastics Industry, Inc., New York. Report No. 2286-51/5.

Owen PE. 1988. Vinyl acetate: 104 week inhalation combined chronic toxicity and carcinogenicity study in the rat and mouse. Report prepared by Hazelton Laboratories Europe Ltd., North Yorkshire, England, for the Society of the Plastics Industry, Inc., NY. Report No. 4661-51/17a. December 1987. [as cited in U.S. EPA, 1995.]

U.S.EPA. 1995. U.S. Environmental Protection Agency. Integrated Risk Information System (IRIS) database. Reference concentration (RfC) for vinyl acetate.